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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/350,043 | 07/08/1999 | FREDERICK L. JORDAN | ORYXE.001A | 7499 |
| 20995 | 7590 | 04/27/2004 | EXAMINER | |
| KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614 | | | GEORGE, KONATA M | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1616 | | |
| DATE MAILED: 04/27/2004 | | | | |

19

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------|----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/350,043 | JORDAN, FREDERICK L. |
| | Examiner | Art Unit |
| | Konata M. George | 1616 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16,19,21-28 and 30-53 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-16,19,21-28 and 30-53 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

Claims 1-16, 19, 21-28 and 30-53 are pending in this application.

Specification

1. Page 12, lines 16 and 19, of the specification contain hyperlinks, which are improper and should be removed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claim 19 contains new matter, as there is no support for the range of delivery agent having a molecular weight of more than 2,000 daltons. Claim 19 also recites “a therapeutically effective amount of a delivery agent”. Applicant’s use of the term “delivery agent” is repugnant to the normal use of the term in that art as well as all the delivery agents discussed in the specification are discussed as actives, for example the capsaicin and NSAIDs are for the treatment of pain and the collagen delivery agents as a cosmetic active. On page 5 of the

specification the applicant defines "delivery agent" as "a molecule of mixture of molecules (e.g., a pharmaceutical or cosmetic agent) that are delivered to the body...can include, for example, a protein, a sugar, a nucleic acid, a chemical or a lipid...glycoproteins, enzymes, genes, drugs and ceramides." It would be more accurately described as the delivered agent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-16, 19, 21-28 and 30-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite and should be rejected under 35 U.S.C. 112, 2nd paragraph as they recite an "ethoxylated lipid selected from the group consisting of castor oil, jojoba oil, corn oil and emu oil". From the specification it is clear that the applicant's intent is to claim ethoxylated castor oil, ethoxylated jojoba oil, etc... but that is not what the claim actually says. This limitation, as written, would be reasonably interpreted as meaning castor oil, etc... are ethoxylated lipids.

4. In view of page 11, lines 8-27, of the specification, applicant's definition of capsaicin renders the limitations of claim 13 vague and indefinite, since oleoresin capsicum is encompassed by the term capsaicin.

Conclusion

5. Claims 1-16, 19 and 21-28 and 30-53 are withdrawn from allowance and now are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (571) 272-0602. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George



Patent Examiner

AV 1616